

US-PAT-NO: 6146380

DOCUMENT-IDENTIFIER: US 6146380 A

(pre)

TITLE: Bent tip electrical surgical probe

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TITLE - TI (1):
Bent tip electrical surgical probe

Brief Summary Text - BSTX (6):

The SMK Needle electrodes from Radionics are in some ways representative of electrodes typically used in pain relief procedures. The SMK Needles have plastic hubs and metal shafts that are insulated over most of their length. An exposed tip is a straight extension of the metal tubing shaft of the needle. An obturating stylet is inserted into the needle during insertion into the patient's tissue. Once it has been inserted, the stylet is withdrawn and the radio-frequency or stimulation probe is inserted. The probe is connected to an external signal generator. Contrast agents or anesthetic fluids can be injected into the tissue near the tip through the hollow needle.

Brief Summary Text - BSTX (7):

A common use for the Radionics SMK Needle is in the stimulation and denervation of a patient's spine. In this procedure, the SMK Needle electrodes are inserted, while viewed via X-ray or fluoroscope, near the facet joints or other neural structures of the spine. Anesthetic or diagnostic localization agents can be injected through the needles, and stimulation testing can then be performed. Radio-frequency heat ablation of a portion of the patient's tissue near the tip of a needle is routinely performed. Hence, proper placement of the needle tip in the complicated structure of a patient's spine requires great skill by the treating clinician. One limitation of the straight electrodes typically used in such procedures is that the needles may need to be withdrawn and re-inserted multiple times to achieve the proper target region for the needle tip.

Brief Summary Text - BSTX (8):

The need to access other complex structures, such as lumbar-sacral discs, particularly where there is a high pelvic brim in males and in those individuals having extreme degenerative narrowing, makes needle placement even more difficult. The nerve root in the lower spine may be accidentally impaled; this presents a serious medical risk to the patient. Again, the use of straight, self-penetrating needles is limited somewhat in that the tip is collinear with the needle shaft, so navigating the tip to avoid critical structures requires redirection of the shaft and repeated manipulation. It

would be desirable to facilitate such redirection in ways unachievable by a straight needle, reducing the need to withdraw and reinsert the needles.

Drawing Description Text - DRTX (5):

FIG. 2 includes FIG. 2A and FIG. 2B, which show schematic side elevation and orthogonal view representations of a bent tip needle with a stylet, an electrical probe, and a signal generator; and

Detailed Description Text - DETX (3):

The electrode cannula 10 further comprises a hub 20. The hub 20 is capable of accommodating an electrical probe 22, which includes a segment that is inserted into and received by the shaft 12 of the cannula 10. This physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements.

Detailed Description Text - DETX (4):

An electrical signal is transmitted to a target region within the body portion P by way of a pair of electrical connections 24 and 26. A first electrical connection 24 couples the cannula 10 to an external signal generator 28 by way of the hub 20 and the probe 22. A second electrical connection 26 connects the external signal generator 28 to a reference electrode 30 in contact with the patient's body portion P. As discussed above, the signal generator 28 can be a source of electrical stimulation, pulsed high-frequency stimulation signals, high frequency signals, pulsed radio-frequency output, or other electrical waveforms. The two electrical connections 24 and 26, in cooperation with the cannula 10 and the reference electrode 30, form a complete electrical circuit permitting current flow. For background information on how this has been accomplished in past systems, see E. R. Cosman and B. J. Cosman, "Methods of Making Nervous System Lesions," in R. H. Wilkins and S. S. Rengachary, eds., Neurosurgery, New York: McGraw-Hill (1984), v. III, pp. 2490-98.

Detailed Description Text - DETX (5):

Generally, by the connections set forth above, an output of the signal generator 28 is conveyed via the first electrical connection 24 to the probe 22, the cannula 10, and its tip 14. This causes electrical stimulation or high-frequency heating of tissue near the exposed electrical tip 14. This practice is well known in the arts of stimulation and ablation.

Detailed Description Text - DETX (8):

FIG. 2 shows another embodiment of the present invention. By way of a further explanation of a specific embodiment, FIG. 2 illustrates various additional features of a curved or bent-tipped electrical needle. In an illustrative embodiment, the shaft 34 comprises a hollow metal tube with an insulated portion 36 illustrated by hatched lines, as shown in FIG. 1. The distal curved tip portion 38 is an extension of the metal tube; it defines a permanent or semi-permanent curve that has an at least partially uninsulated

surface portion. In the embodiment illustrated in FIG. 2, the bend is approximately curvilinear and defined by a radial arc. The tip portion 38 of the shaft 34 has a distal pointed end 40, which as described above can be useful in penetrating tough tissue. A hub 42 can be metal, or alternatively plastic when radiotranslucency is desired.

Detailed Description Text - DETX (10):

FIG. 2B is another view of the needle illustrated in FIG. 2A, but additional features are visible. The pointed end 40 defines an opening 46 that is capable, as discussed above, of dispensing diagnostic or therapeutic liquids, or of allowing a stylet or endoscopic instrument to pass. Also shown is an index dot 48 on the hub which indicates the orientation of the bent tip 38. In a preferred embodiment, the index dot 48 is located at the same radial position on the shaft 34 as the bent tip 38 and pointed end 40. An index notch 50, which indexes the stylet and its hub 44 with respect to the shaft 34 and the orientation of the tip 14, is further provided. Index notches such as notch 50 are commonly used in needle and stylet sets. An electrical probe 52 is receivable by the shaft 34 when the stylet is removed; it has a probe shaft 54 and a probe tip 56. In one embodiment of the invention, the probe tip 56 comprises a temperature sensor. See, for example, the SMK needles and cannulae made by Radionics.

Detailed Description Text - DETX (11):

The apparatus illustrated in FIGS. 2A and 2B is used as follows. The cannula 33, with a stylet positioned in the shaft 34, is inserted into the patient's body portion P (FIG. 1) either percutaneously or intraoperatively. An X-ray viewer (comprising a source S and an image detector I, as disclosed above) can verify the position and orientation of the bent tip 38 in relation to desired anatomical targets. The stylet is then removed, and the probe 52 is inserted into the shaft 34. The probe 52 is connected to the signal generator 58, and the process of electrical stimulation, high-frequency heating, or other electrical application can be made. Electrical signals from the signal generator 58 are communicated to the exposed distal tip 38 by way of contact between the probe shaft 54 and an internal lumen defined by the electrode shaft 34. If the electrode shaft 34 or cannula is a metal tube and the probe shaft 54 has a metal outer surface, then this can be accomplished simply through physical contact between the probe shaft 54 and the electrode shaft 34. When the application of therapeutic electrical signals is complete, the probe 52 is withdrawn from the cannula 33, and the electrode can then be withdrawn from the patient.

Detailed Description Text - DETX (18):

A further advantage of using a small-gauge spinal needle with a curved or bent distal end is that it can be accurately steered into narrow and relatively difficult-to-access portions of a patient's spine. For example, access to the lumbar sacral disc is often difficult with straight needles, especially with the high pelvic brim in males and the extreme degenerative narrowing seen in the bony structures of some patients. In these situations, the use of a straight-tipped needle can increase the risk of L5 nerve root puncture or

injury. With the present invention and a curved-tipped spinal needle, this danger can be avoided and the risks thereby minimized. The bent tip enables a curved approach to the spinal structures and the intravertebral disc. It facilitates the placement of the curved tip in such a way as to hug or conform the outer aspect of the superior articular facet. Moreover, the curved needle of the present invention can be steered around corners, underneath bone grafts, and past spinal fixation devices such as metal plates that may have been implanted on the spine in previous surgical procedures.

Detailed Description Text - DETX (27):

In some situations, a sharp needle (such as those illustrated in FIGS. 1 and 2) may be easier to insert or manipulated. For example, in a conscious patient, a pointed needle is inserted more comfortably, whereas for a sedated patient a blunt-tipped needle may be used. In another context, the medial branch of the superior ramus is better approached with a sharp-tipped needle or cannula because major neural structures do not lie in the desired pathway to the lumbar transfer process or the waste of the articulate pillar in the cervical spine. In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38, in contrast to the inside wall used for the window 72 of FIG. 3.

Detailed Description Text - DETX (29):

It should be noted that the terms needle, probe, cannula, etc. as used herein all denote medical and surgical tools that can accommodate the bent tip structure disclosed and claimed. There is no intention to restrict any particular embodiment of the invention to fewer than all of the foregoing implements. Furthermore, certain exemplary clinical applications have been discussed herein as those in which the invention can be successfully employed to the clinician's advantage. However, the invention is not limited to use in such applications, and other medical and surgical procedures would be apparent to a practitioner of ordinary skill.

Claims Text - CLTX (11):

7. The cannula of claim 1, wherein the electrical connection comprises a probe adapted to be received by the shaft.

US-PAT-NO: 5624379

1025

DOCUMENT-IDENTIFIER: US 5624379 A

TITLE: Endoscopic probe with discrete rotatable tip

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Abstract Text - ABTX (1):

An endoscopic probe has an elongate flexible member and a radially extending tip rotatably mounted on a remote end thereof. A wire extends through the elongate flexible member and into the tip. The wire rotates relative to the elongate flexible member to rotate the radially extending tip to any desired orientation about the axis of the elongate flexible member.

TITLE - TI (1):

Endoscopic probe with discrete rotatable tip

Brief Summary Text - BSTX (2):

The present invention relates to medical devices and more particularly, to an endoscopic probe having a remote tip which is rotatable and biased to extend radially from the axis of rotation.

Brief Summary Text - BSTX (5):

As can be appreciated by anyone who has attempted to unlock a car door with a coat hanger, it is one thing to get the coat hanger into proximity with the door latch, and it is quite another to hook the latch and pull it open. The same can be said for operation of an endoscopic probe of the type described above, particularly when one recognizes that the probe must be inserted through a tube and yet perform a task on a body part that is typically radially displaced from the axis of the tube. In other words, the endoscope gets the biopsy jaws down into the patient's esophagus, but the tissue may be off to the side. One approach to overcome this problem has been to deflect the endoscope to aim the biopsy jaws in the desired direction. However, the size of the endoscope and/or anatomical constraints place significant limitations on this practice.

Brief Summary Text - BSTX (6):

U.S. Pat. No. 4,945,920 discloses a device having a radially extending tip which can be maneuvered relative to a patient by rotating the entire device within the endoscope. However, this device is difficult to operate because rotation of the entire device can cause "twist" to accumulate, and friction between the device and the endoscope makes it difficult to effect incremental movements of the remote tip. In other words, the torque tends to build along

the device until resistance due to static friction is overcome, at which point the relative smaller resistance due to kinetic friction allows the torque to be released essentially all at once, thereby causing whipping of the distal portion of the device. Thus, a need remains for an endoscopic probe that is easy to operate and effective in use.

Brief Summary Text - BSTX (8):

A preferred embodiment of the present invention provides an endoscopic probe having a tip that rotates about the longitudinal axis of the probe and extends radially therefrom. An elongate flexible member extends from a handle to a remote end which is connected to the tip by means of a swivel. A wire extends through the flexible member and the swivel and into the radially extending tip. A rotating portion of the handle is rotated relative to a base portion of the handle to rotate the tip relative to the flexible member. A tool, such as biopsy jaws, may be selectively connected to the remote end of the wire, proximate the distal end of the tip, such that the tool may be operated by axial movement of the wire relative to the flexible member.

Drawing Description Text - DRTX (3):

FIG. 1 is a plan view of a preferred embodiment probe constructed according to the principles of the present invention;

Drawing Description Text - DRTX (4):

FIG. 2 is a sectioned plan view of a remote end of the preferred embodiment probe of FIG. 1;

Drawing Description Text - DRTX (6):

FIG. 4 is a sectioned fragmentary view of a wire extending through the preferred embodiment probe of FIG. 1;

Detailed Description Text - DETX (2):

A preferred embodiment endoscopic probe constructed according to the principles of the present invention is designated as 100 in FIGS. 1-7. The preferred embodiment probe 100 is designed specifically for taking a biopsy sample from a person's esophagus. However, those skilled in the art will recognize that the present invention is not limited to this particular application. For example, similar probes could be used in any of various procedures in which an endoscope or other relatively stiff tube provides access to an internal portion of a patient's body, including cardiac, gastrointestinal, urological, pulmonary, orthopedic, general surgery, ENT, laparoscopy, and/or radiology procedures.

Detailed Description Text - DETX (3):

As shown in FIG. 1, the probe 100 includes a handle 110 having a plunger or sliding portion 112, a base portion 116, and a rotating portion 124, each of which is made of plastic. The sliding portion 112 includes a central body 113

and a pair of closed loops 114 extending from opposite sides thereof. Each of the loops 114 is sized and configured to receive a person's finger. The base portion 116 includes a shaft 120 disposed within and slidable relative to the body 113 of the sliding portion 112. Connected to one end of the shaft 120 is a closed loop 118 which is sized and configured to receive a person's thumb. Connected to an opposite end of the shaft 120 is another closed loop 122.

Detailed Description Text - DETX (5):

As shown in FIGS. 1-2, the probe 100 further includes an elongate flexible member 130 which extends from a first end 138, proximate the handle 110, to a second, remote end 136. The first end 138 is anchored to the sliding portion 112 of the handle 110. In the preferred embodiment 100, the elongate flexible member 130 is at least one meter long and includes a coil of stainless steel wire 132 disposed within a polyurethane tube 134. Those skilled in the art will recognize that the plastic tube 134 is optional and that both it and/or the elongate flexible member 130 could be made from other suitable materials. Moreover, the length of the elongate flexible member 130 may vary according to its intended application.

Detailed Description Text - DETX (6):

The probe 100 further includes a curved tip 140 which extends from a first end 146, proximate the remote end 136 of the elongate flexible member 130, to a second, distal end 144. In the preferred embodiment 100, the curved tip 140 is less than ten centimeters in length and includes a teflon tube 143 disposed within a polyurethane tube 142. Those skilled in the art will recognize that the tip 140 could be made from other suitable materials. The curved tip 140 is preformed to assume a shape substantially as shown in FIG. 2, wherein a first segment 147 is a generally co-linear extension of the elongate flexible member 130, and a second segment 148 extends generally transverse to the first segment 147. Although the preferred embodiment segments 147 and 148 extend perpendicular to one another, those skilled in the art will recognize that this preformed angle, as well as the overall length of the tip 140, may vary according to the application for which it is intended. Also, a stainless steel coil 149 may be disposed within the second segment 148 to enhance structural integrity. The stainless steel coil 149 occupies a portion of the plastic tube 142 exclusive of the teflon tube 143. The curved tip 140 is sufficiently resilient to accommodate substantial straightening thereof and then to subsequently return to its preformed, generally L-shaped configuration.

Detailed Description Text - DETX (7):

A tool 150 is supported by the curved tip 140 proximate its distal end 144. In the preferred embodiment 100, the tool 150 includes a pair of biopsy jaws 152 and a capsule 154. The jaws 152 are pivotally connected to one another and open and close to collect a tissue sample. Those skilled in the art will recognize that numerous other tools could be substituted for the biopsy jaws 152 and the capsule 154 shown in FIG. 2. For example, the probe 100 could be fitted with any of various retrieval devices, sewing devices, needles, snares, knives, scissors, etc.

Detailed Description Text - DETX (12):

As shown in FIG. 3, the wire 160 extends through the tube 176 and into the curved tip 140. Torque applied to the rotating portion 124 of the handle 110 causes the wire 160, the sleeve 172, and the curved tip 140 to rotate relative to the elongate flexible member 130, the tube 176, and the ball 174. With a tip 140 that is both curved and freely rotatable, the probe 100 is easy to use and suitable for a variety of endoscopic procedures. Also, the tip 140 may be provided in different sizes and/or configurations according to the parameters for different procedures. Those skilled in the art will also recognize that any given tip will tend to direct the biopsy jaws or other tool at a substantially constant angle regardless of the orientation of the tip relative to the flexible member.

Detailed Description Text - DETX (14):

Operation of the probe 100 is described with reference to an esophageal biopsy procedure, several steps of which are illustrated in FIGS. 5-7. An endoscope 90, which may be described as a relatively stiff tube or device defining a lumen, is inserted down the esophagus 80 of a patient, and then the probe 100 is fed through the endoscope 90. The length of the second segment 148 is greater than the diameter of the relatively stiff tube 90. As shown in FIG. 5, the tip 140 is temporarily straightened to facilitate passage through the endoscope 90. As shown in FIG. 6, the tip 140 returns to its preformed configuration upon exiting the remote end of the endoscope 90. The curvature of the tip 140 places the biopsy jaws 152 at a desirable angle relative to the sidewalls of the persons esophagus 80 and also provides immediate access to radially displaced portions thereof. As shown in FIG. 7, the tip 140 is then rotated about the axis of the flexible member 130 (by rotating the ball 124 on the handle 110) to arrive at the desired tissue location 88. Next, the jaws 152 are opened and closed (by sliding the plunger 112 on the handle 110 back and forth) to collect the tissue sample. Finally, the probe 100 is withdrawn from the endoscope 90, which in turn, is withdrawn from the patient's esophagus 80.

Claims Text - CLTX (1):

1. A medical probe of a type inserted through an endoscope having a longitudinal axis, comprising:

Claims Text - CLTX (5):

2. A medical probe according to claim 1, wherein said second member is made of a resilient material and preformed to assume a curved configuration when unstressed.

Claims Text - CLTX (6):

3. A medical probe according to claim 1, wherein a torque transmitting member is disposed within said elongate flexible member, and said torque transmitting member has a user accessible end and a remote end, and said remote end of said torque transmitting member is connected to said second member in

such a manner that rotation of said user accessible end of said torque transmitting member causes rotation of said second member.

Claims Text - CLTX (7):

4. A medical probe according to claim 3, wherein said torque transmitting member is a stainless steel wire.

Claims Text - CLTX (8):

5. A medical probe according to claim 3, wherein said torque transmitting member is a hollow wire.

Claims Text - CLTX (9):

6. A medical probe according to claim 3, wherein a ball and socket are interconnected between said second member and said remote end of said elongate flexible member.

Claims Text - CLTX (10):

7. A medical probe according to claim 3, wherein said torque transmitting member is axially movable relative to said elongate flexible member.

Claims Text - CLTX (11):

8. A medical probe according to claim 7, further comprising a tool connected to said remote end of said torque transmitting member and operable in response to axial movement of said torque transmitting member relative to said elongate flexible member.

Claims Text - CLTX (12):

9. A medical probe according to claim 3, wherein said torque transmitting member has a relatively larger diameter proximate said user accessible end thereof, and said torque transmitting member has a relatively smaller diameter proximate said remote end thereof.

Claims Text - CLTX (13):

10. A medical probe according to claim 1, wherein a ball and socket are interconnected between said second member and said remote end of said elongate flexible member.

Claims Text - CLTX (14):

11. A medical probe according to claim 1, wherein said second member is resilient, and said second member deforms toward a relatively more straight configuration during passage through the endoscope, and said second member returns to a relatively more curved configuration upon exiting the endoscope.

Claims Text - CLTX (15):

12. A medical probe according to claim 11, wherein when said second member returns to said relatively more curved configuration upon exiting the endoscope, a distal section of said second member extends substantially perpendicular to said elongate flexible member proximate said remote end thereof.

Claims Text - CLTX (16):

13. A medical probe according to claim 1, further comprising a tool supported by a distal end of said second member.

Claims Text - CLTX (17):

14. A medical probe according to claim 13, wherein said tool is oriented at an angle relative to a remote portion of said elongate flexible member, and said angle tends to remain substantially constant during rotation of said second member.

Claims Text - CLTX (18):

15. A medical probe according to claim 1, wherein said elongate flexible member includes a stainless steel coil.

Claims Text - CLTX (19):

16. A medical probe according to claim 15, wherein said stainless coil is nested within a plastic tube.

Claims Text - CLTX (20):

17. A medical probe according to claim 1, wherein said second member includes a teflon tube nested within a plastic tube.

Claims Text - CLTX (21):

18. A medical probe according to claim 17, wherein said second member further includes a stainless steel coil nested within a portion of said plastic tube exclusive of said teflon tube.

Claims Text - CLTX (22):

19. A medical probe according to claim 1, further comprising a handle connected to said user accessible end of said elongate flexible member.

Claims Text - CLTX (23):

20. A medical probe according to claim 19, further comprising biopsy jaws operatively connected to said handle in such a manner that relative movement between a first handle member and a second handle member causes movement of said biopsy jaws relative to one another.

Claims Text - CLTX (24):

21. A medical probe according to claim 20, wherein relative movement between a third handle member and said second handle member causes rotation of said second member.

Claims Text - CLTX (25):

22. A medical probe according to claim 1, wherein a ball is secured to said remote end of said elongate flexible member, and a wire extends through at least a portion of said elongate flexible member, and through said ball, and through at least a portion of said second member.

Claims Text - CLTX (26):

23. A medical probe according to claim 22, wherein a sleeve has a first end which forms a socket about said ball, and said sleeve has a second, opposite end which is secured to said second member, and said wire, said sleeve, and said second member rotate as a unit relative to said ball and said elongate flexible member.

Claims Text - CLTX (27):

24. A medical probe according to claim 23, wherein a tube extends through said ball and a portion of said elongate flexible member, and said wire extends through said tube.

Claims Text - CLTX (28):

25. An endoscopic probe, comprising:

Claims Text - CLTX (34):

26. An endoscopic probe according to claim 25, wherein a curved resilient member is interconnected between said ball and socket joint and said tool, and said second elongate flexible member extends through said curved resilient member.

Claims Text - CLTX (35):

27. An endoscopic probe according to claim 25, wherein said handle includes a base portion and a rotating portion, and said second elongate flexible member is operatively connected to said rotating portion, and rotation of said rotating portion relative to said base portion causes rotation of said second elongate flexible member and said tool relative to said first elongate flexible member.

Claims Text - CLTX (36):

28. An endoscopic probe according to claim 27, wherein said handle further includes a sliding portion, and said second elongate flexible member is secured operatively connected to said sliding portion, and sliding of said sliding

portion relative to said base portion actuates said tool.

Claims Text - CLTX (37):

29. An endoscopic **probe** according to claim 25, wherein said tool includes a pair of biopsy jaws pivotally mounted relative to one another.